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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,651	10/08/2003	Lawrence A. Shimp	2004367-0029	7263
24280	7590	08/14/2006	EXAMINER	
CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			KENNEDY, SHARON E	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/681,651	Applicant(s) SHIMP ET AL.	
	Examiner Sharon E. Kennedy	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/02/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
 4a) Of the above claim(s) 1-33, 45-47, 54, 55 and 59-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-37, 39-41, 44, 48-52 and 56-58 is/are rejected.
- 7) ☒ Claim(s) 38, 42-43 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/07/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Election/Restrictions

Applicant's election without traverse of Group V in the reply filed on March 2, 2006 is acknowledged. Claims 1-33, 45-47, 54, 55, 59-84 are withdrawn from consideration.

Claim Rejections - 35 USC § 102

Claims 34, 35, 39-41, 44, 52 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brennan et al., US 6,399,693. Note is made of applicant's cited reference and the discussion thereof in applicant's specification, published version, page 2, beginning the last line of column 1 to end of [0011] in column 2. Regarding claim 34, the examiner takes the position that the disclosure in '693 at especially column 4, line 38 ("bone") and column 4, line 44 "particulate" anticipates the claimed bone-polymer composite comprising bone particles. This bond is covalent (column 4, line 50). The silane coupling agents are disclosed throughout the '693 document. Regarding claim 35, this list includes all the possible types of bone materials and is therefore anticipated by Brennan's general description of bone. Regarding claim 39, note "Q" in column 4, lines 8-9, especially also lines 15-29. Regarding claims 40, 41 and 44, see column 3, lines 37-49. Regarding claim 52, see column 2, line 28, which

discloses that the structure is cross-linked. The examiner takes the position that the network of moieties reactive with the silane (column 2, line 47, etc.) anticipates the claimed cross-linking agent.

Claim Rejections - 35 USC § 103

Claims 36, 37, 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan et al., '693. Claim 36 is directed to a particular source of bone, claim 37 is directed to pretreated types of bone material. Brennan is silent on these issues. Regarding claim 36, the examiner takes the position that the source of the bone is obvious to one of ordinary in the art dependent upon the ultimate use of the bone composite material. Regarding claims 37, 48-51, pretreating the bone particles, especially for xenogenic or allogenic bones, is considered a necessary, obvious part of preparing any bone transplant which might result in rejection.

Claims 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan et al., '693 in view of Laurencin et al., US 5,626,861. Brennan is silent as to the additives useful in the bone composition. Laurencin is cited to exemplify that the use of antibiotics, chemotherapeutics, bone cell stimulators, osteoblasts, etc., (see Laurencin, claims 3, 5 and 10) are well known in the art. It would be obvious to one of ordinary skill in the art at the time the invention was made to add these rudimentary ingredients as needed to help mold the composition or make it function as a drug delivery device, dependent on the environment of use or patient need.

Allowable Subject Matter

Claims 38, 42, 43, 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Regarding claim 38, none of the prior art shows or suggests the percentage of bone particles in combination with the other claimed ingredients. Brennan mentions that bone particles may be included, but fails to quantify the amount. Note is made of Brennan's Example 6, column 7, showing a sample composite preparation, however, the weight percents are given for bioactive glass particulates. This does not show or suggest a weight percent for the bone particles in view of the dissimilarities. Regarding the polymer selected from polysaccharides, starch, dextran, etc., none of the prior art shows or suggests the silane coupling agent with the bone particles in combination with these polymers. Regarding claim 53, the cross-linking agent type is neither shown nor suggested by the prior art, in combination with the other claimed embodiments.

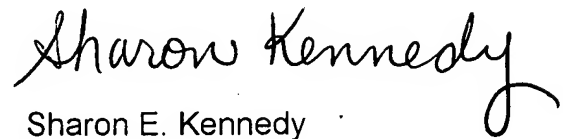
Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon E. Kennedy
Primary Examiner
Art Unit 1615